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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,289	08/15/2000	Mahendra G. Dedhiya	10/042	1566

7590 07/09/2002

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EXAMINER

WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/09/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/639,289

Applicant(s)

DEDHIYA ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 17.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 and 7-22 are pending. The Amendment filed April 18, 2002, amended claims 1 and 7, and cancelled claims 5-6.

Request for Continued Examination

The request filed on 4/18/02 for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/639289 is acceptable and an RCE has been established. An action on the RCE follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 9-10 and 12-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) The terms "stable" and "enhanced" in claim 1 (part (ii)) are relative terms which renders the claim indefinite. The terms "stable" and "enhanced" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(ii) The terms "stable" and "rapid" in claim 9 (line 2) are relative terms which render the claim indefinite. The terms "stable" and "rapid" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(iii) The term "suitable liner" in claim 10 line 2 is vague and indefinite, as the term is bother relative and confusing. What is suitable? What defines a suitable liner from an unsuitable liner? What are suitable liners for amber glass? The specification does not define such liners and one of ordinary skill in the art would not be apprised of them.

(iv) Claim 12 recites the limitation "The composition of claim 1, wherein the alcohol". There is insufficient antecedent basis for this limitation in the claim.

(v) Claim 13 recites the limitation "The composition of claim 1, wherein the glycol". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 7-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (5,716,638) in view of Patel et al. (6,294,192) in further view of LaMastro et al. (5,258,336).

Touitou teaches medical compositions for topical application to the skin. Disclosed is a composition comprising 7uci/ml tetrahydrocannabinol, 49% ethanol, 19.6% propylene glycol, and 29.4% water. It is further disclosed that ethanol can comprise 15-30% of the composition, propylene glycol can comprise up to 20% of the composition, and water can comprise at least 20% of the composition. The composition particles are disclosed as having a size ranging from .01-8.2 um. See Col. 1, line 11-Col. 3, line 25. The reference fails to teach aerosolization, preferred ratios and dosages, and containers.

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Patel et al. teach triglyceride-free pharmaceutical compositions for delivery of hydrophobic therapeutic agents. Disclosed are composition comprising a hydrophobic therapeutic agent and a carrier, wherein the carrier is formed from a combination of a hydrophilic surfactant and a hydrophobic surfactant. The hydrophobic therapeutic agent is disclosed as comprising 0.1-60% by weight of the composition. Tetrahydrocannabinol is disclosed as a therapeutic agent. Ethanol and propylene glycol are disclosed as preferred solubilizers that can be combined in composition. The solubilizer is disclosed as comprising 1-100% of the composition. Dosage forms wherein the composition is dispersed with water are disclosed. The composition can take on the form of a spray or an aerosol for pulmonary administration. Human administration is disclosed as preferable. See Col. 4, line 50-Col. 5, line 8; Col. 21, lines 47-line 67; Col. 24, line 59-Col. Col. 26, line 60; Col. 28, lines 14-40; Col. 30, lines 25-35; Col. 31, lines 1-35.

LaMastro et al. teach low expansion type 1 amber glass containers. These containers are disclosed for holding pharmaceutical preparations that require packaging that provides a high degree of chemical stability and protection from ultraviolet light. See Col. 1, lines 10-19 and lines 62-68.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of Touitou in the form of an aerosol, as taught by Patel et al. because a) Patel et al. and Touitou both teach compositions comprising THC, ethanol, propylene glycol, and water; b) Patel et al. teach topical, transdermal, and aerosol forms of the composition as possible and interchangeable, and Touitou teach topical, and transdermal forms of his

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composition; hence, the replacement of one pharmaceutical form (topical) of the composition for the other (aerosol) for pharmaceutical purposes would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of the combined references in the type 1 amber glass container of LaMastro et al. because a) the combined references teach a composition in the form aerosol, and a composition that results in aerosolization must be housed in a closed container; thus since LaMastro et al. teach their containers for pharmaceutical use and as providing a high degree of chemical stability and protection from ultraviolet light, teaching the container of the combined references as a type 1 amber container would be within the skill of one of in the art.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 8-11 of the specification have been considered but not found persuasive because the data merely demonstrate the stability of the instant composition over time. This is seen to be an expected result based on the cited prior art.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
June 13, 2002

RUSSEL TRAVERS
PRIMARY EXAMINER
GROUP 1200